EXHIBIT B1-A

NEW YORK SUPREME COURT
COUNTY OF ALBANY

People of the State of New York, Plaintiffs, v. Pharmacia Corp., Defendant.	:	Index No. 904-03
People of the State of New York, Plaintiffs, v. GlaxoSmithKline, P.L.C., et al., Defendants.	:	Index No. 905-03
People of the State of New York, Plaintiffs, v. Aventis Pharmaceuticals, Inc., Defendant.	:	Index No. 1150-03

CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTIONS TO DISMISS

Dated: December 1, 2003

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATE CASES

FEDERAL STATUTES

STATE STATUTES

OTHER AUTHORITIES

Introduction and Summary of Argument

The State of New York, in three separate complaints that have been consolidated in this Court, seeks injunctive relief and damages against Aventis Pharmaceuticals Inc., Pharmacia Corporation and GSK.[1] The defendants submit this Consolidated Memorandum in support of their respective Motions to Dismiss the State's complaints.

In these cases, the State seeks to recover: (a) allegedly excessive payments made by the State to physicians and pharmacies to reimburse them for purchases of defendants' prescription drugs under the New York Medicaid and Elderly Pharmaceutical Insurance Coverage ("EPIC") programs; and (b) allegedly excessive co-payments made by New York citizens to physicians and pharmacies under those programs, as well as under the federal Medicare program. The State asserts various causes of action against the defendants for fraudulently and deceptively reporting drug pricing information to third-party commercial price reporting services, who, according to the State, then took the defendants' reported pricing information and used it to determine and publish an inflated "Average Wholesale Price" ("AWP") for the defendants' prescription drugs. According to the State, the third party publishers' allegedly inflated AWPs were then used by the federal Medicare and State Medicaid and EPIC programs to determine the programs' drug reimbursement rates.

The gravamen of the State's claims is that all of the government programs were deceived into reimbursing doctors and pharmacies at reimbursement rates that were inflated because the

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[1] SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), is one of the three so-called "GSK defendants" named in Complaint No 905-03. Named defendant GlaxoSmithKline, plc, a foreign holding company, has not yet been properly served under the Hague Convention and no appearance has been made on its behalf. Named defendant Glaxo Wellcome Inc. no longer exists, as it was previously merged into SmithKline Beecham Corporation to form SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), and therefore no appearance has been entered on its behalf either.

government set those reimbursement rates based on the commercially reported AWPs, thinking the AWPs were actual prices at which drugs were purchased by providers. The basis of the State's co-payments claims is derivative; that is, the State contends that because the state and federal governments were deceived into setting inflated AWP-based reimbursement rates, New York citizens made corresponding co-payments to physicians and pharmacies that were also inflated.

The State's core claim that the government was deceived by published AWPs into over-reimbursing physicians and pharmacists who participated in the Medicaid, EPIC and Medicare programs is wholly without merit. First, there are important distinctions between these programs that impose limitations on the State's claims. New York's Medicaid and EPIC program reimburse ***pharmacists*** for drugs they dispense on the basis of AWPs. But Medicaid reimburses ***physicians*** for drugs they administer on the basis of actual acquisition cost, and EPIC does not cover physician-administered drugs. Moreover, patient co-payments under Medicaid and EPIC are fixed and therefore are not affected by AWPs. By contrast, the federal Medicare program, which only covers physician-administered drugs, reimburses physicians at a percentage of AWP, and the beneficiary is responsible for a percentage co-payment. Thus, AWPs are relevant only to (1) the State's claims for money it paid through Medicaid or EPIC for drugs dispensed by pharmacists, and (2) the State's claims on behalf of Medicare beneficiaries for the co-payments they made for physician-administered drugs.

Second, the State's claim that government officials were deceived into thinking that published AWPs represented actual provider acquisition costs is flatly contradicted by decades of government reports and public statements -- including statements by senior agency officials,

legislators, the press and even a former President. ***The government reports and public statements all show that for years AWPs have been well understood throughout the industry and by federal and state agencies to be "sticker prices" that were significantly higher than the prices at which drugs could be purchased by doctors and pharmacies in the marketplace.*** That same public record also shows that, with this understanding, Medicare and Medicaid officials chose, for a variety of well-articulated policy reasons, to reimburse for some drugs at AWP-based rates that were known to be above the providers' actual acquisition costs. Although the State ignores this vast public record, it is fatal to any claim that the State or federal government was deceived by published AWPs, requiring dismissal pursuant to CPLR § 3211(a)(7) and § 3211(a)(1).

Moreover, the State's derivative claims aimed at recovering co-payments made by New York Medicaid, EPIC and Medicare beneficiaries cannot succeed either. Drug co-payments of New York Medicaid participants are set at small flat dollar amounts that are totally unaffected by the amount of any alleged AWP-based over-reimbursements the State itself paid under Medicaid. EPIC co-payments are set at flat amounts as well.[2] Accordingly, none of the State's claims can proceed to the extent the State is seeking to recover on behalf of Medicaid and EPIC participants who made co-payments. Medicare beneficiaries (by contrast) are responsible for 20% of the AWP-based Medicare reimbursement amount. But to the extent their 20% co-payments are higher than they would have been if Medicare had chosen to reimburse for drugs under a formula other than the AWP-based one it selected, the higher co-payments were not the result of any

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[2] *See* pp. 16-17 below.

deception by the defendants, but were due to repeated and conscious policy choices by Congress to set Medicare reimbursement rates (and the consequent 20% co-payments) at the chosen levels.

Besides ignoring the statutes and regulations governing State physician reimbursements and co-payments -- as well as the lengthy public record relating to AWPs -- the State's complaints suffer from another fundamental flaw that requires dismissal. They are utterly devoid of specific factual allegations that place the defendants on notice of exactly what the State seeks to place at issue in this litigation. The complaints each name only a few drugs that are the subject of its claims. Most, if not all, of the named drugs are part of a small and somewhat atypical group of drugs that are administered by physicians and covered by Medicare Part B, as opposed to prescription pharmaceuticals that are generally self-administered and dispensed in the very different retail pharmacy market. The State's complaints do not inform the defendants which, if any, of defendants' hundreds of ***other*** (non-Medicare Part B) drugs are the subject of its allegations -- leaving defendants (and the Court) to guess about which drugs sold in which markets are the subject of the State's allegations. In addition, the State does not:

- provide a single AWP (or other piece of pricing data) for any drug that is alleged to be inflated, deceptive or fraudulent;[3]
- provide a single instance of a deceptive act or false statement; or
- provide a single example of a commercial bribe or a kickback.

Instead, the State brings sweeping and serious deceptive acts and practices, fraud, bribery and kickback claims based on conclusory allegations and vague theories. New York's pleading rules do not allow such unspecific claims to proceed.

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[3] As discussed below, other courts presiding over "AWP" cases have refused to allow such general, non drug-specific allegations to proceed.

In addition to these over-arching flaws in the State's complaints, each of the State's five causes of action suffers from numerous other deficiencies.

In its First Cause of Action, the State claims that the defendants' actions constituted deceptive business practices in violation of General Business Law § 349. This claim fails because the defendants' alleged practices were not deceptive as a matter of law; the defendants' alleged actions were not consumer oriented as required to be a violation of the statute; and the defendants' conduct was not the cause of any injury to Medicaid, EPIC or Medicare co-payors. Any overpayments allegedly made were the result of multiple intervening causes, not the defendants' reporting of pricing information to third party price publishing services.

In its Second Cause of Action, the State asserts that the same allegedly deceptive price reporting constituted "repeated and persistent fraud," in violation of Executive Law § 63(12). This claim fails for essentially the same reasons as the State's deceptive practices claim fails.

In its Third Cause of Action, the State maintains that defendants repeatedly violated Executive Law § 63(12) by engaging in commercial bribery of physicians. According to the State, by creating a "spread" between the amounts physicians actually paid for a drug and the amounts at which they were reimbursed, the defendants conferred a benefit upon a fiduciary (the physician) without his principal's (the patient's) consent, thus allegedly violating the commercial bribery statute. Although the State claims that these alleged acts of commercial bribery were repeated and persistent, the State ***fails to identify a single instance of an alleged bribe*** by any defendant, requiring dismissal for lack of specificity alone. Moreover, this claim fails insofar as EPIC is concerned because physicians do not participate in the EPIC program. It also fails insofar as it is based on physician-administered drugs covered by the New York Medicaid

program because that program reimburses physicians for such drugs at their actual acquisition cost, not at a higher AWP-based amount. This count does not allege any bribery of pharmacists who sell self-administered drugs. Thus, the commercial bribery claims can apply only to claims made by the State on behalf of Medicare beneficiaries for Medicare Part B covered drugs sold to physicians. Yet even with respect to this limited type of claim, the Third Cause of Action also fails because (a) the State does not and cannot allege that defendants' activities interfered with (or were intended to interfere with) any physicians' fiduciary duty to his patients to provide quality care, an essential element of the claim, and (b) the State does not allege that defendants -- as opposed to the government -- caused a benefit to be conferred on physicians through Medicare's AWP-based reimbursement scheme.

In its Fourth Cause of Action, the State asserts that defendants repeatedly violated Executive Law § 63(12) in that they engaged in conduct prohibited by New York's Medicaid anti-kickback regulations by offering payments to New York pharmacies in return for "purchasing, . . . ordering or recommending any medical care, services, or supplies for which payment is claimed under the program." This claim lacks particularity, as it ***fails to identify a single alleged kickback*** related to a single drug sale, and must be dismissed for this reason alone. Moreover, this cause of action is limited to claims relating to the defendants' alleged marketing to retail pharmacists of drugs reimbursed by the New York Medicaid program. Even as to this limited type of claim, the cause of action fails because (1) the kickback theory apparently being alleged makes no economic sense as applied to brand name drugs sold in the retail pharmacy market, and (2) the State's core contention that defendants marketed secret discounts to

pharmacists is belied by the fact that the defendants each reported pricing information to the State that effectively disclosed any such discounting.

Finally, in its Fifth Cause of Action, the State alleges that defendants repeatedly violated Executive Law § 63(12) in that they obtained public funds from the State Medicaid and EPIC programs by making false statements about drug prices in the retail pharmacy market. Again, the claim fails because the State does not identify a single false statement relating to a single drug. This cause of action also fails for the fundamental reasons that (a) there was no fraud or deception, given the public record, (b) it is not alleged that defendants obtained a penny of public funds (the States reimbursements went to pharmacies), and (c) the pharmacies' alleged receipt of over-reimbursements was not caused by the defendants, but by multiple intervening acts, including the State programs' own reimbursement decisions.

To aid the Court's analysis of all of these issues, we begin with an outline of the law and regulations governing Medicaid, EPIC and Medicare prescription drug reimbursements, as well as a discussion of the regulatory and legislative history of AWPs and the longstanding public debate concerning their use as a benchmark for government drug reimbursement schemes.

I. REGULATORY AND LEGISLATIVE BACKGROUND

The public record squarely refutes the State's contention that it and the federal government were deceived when they set prescription drug reimbursement rates on the basis of AWPs reported by commercial price reporting services. That record -- which spans several decades and includes numerous governmental studies, testimony before Congress and press reports -- demonstrates that AWPs were understood throughout the industry and by Medicaid and Medicare officials to be undiscounted list prices or "sticker prices" which generally did ***not***

reflect what was being paid in the market. Government payors who chose AWPs as reimbursement benchmarks did so for a variety of policy reasons, with the understanding that by doing so they would generally be paying more -- sometimes substantially more -- for drugs than the providers paid themselves.[4]

A. Medicaid and EPIC

1. The Federal Regulations Governing Medicaid

Under the Medicaid program, the federal government reimburses a substantial portion of the States' costs for providing medical assistance to qualifying low-income persons. *See* 42 U.S.C. § 1396 *et seq*. (2003). All 50 states, including New York, have Medicaid programs that provide a prescription drug benefit.[5] In contrast to the federal ***Medicare*** program, which has historically covered only limited categories of drugs under Part B of the program, the state

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[4] On a motion to dismiss pursuant to CPLR 3211(a)(7), courts may take judicial notice of government documents or other publicly available documents and thereby "read them into the complaint." *St. Regis Tribe of Mohawk Indians v. State*, 5 N.Y.2d 24, 36, 152 N.E.2d 411, 417, 177 N.Y.S.2d 289, 297 (1958) (affirming dismissal based, *inter alia*, on reports of legislative committees); *see also, Cricchio v. Pennisi*, 90 N.Y.2d 296, 683 N.E.2d 301, 660 N.Y.S.2d 679 (1997) (judicial notice of memorandum issued by Health Care Financing Administration); *Carey v. New York Cent. R. Co.*, 250 N.Y. 345, 165 N.E. 805 (1929) (Cardozo, J.) (Federal Trade Commission report on grain); *Sommers v. Sommers*, 203 A.D.2d 975, 611 N.Y.S.2d 971 (4th Dep't 1994) (government inflation statistics); *Matter of Wood*, 177 A.D.2d 161, 581 N.Y.S.2d 405 (2d Dep't 1992) (prices in Wall Street Journal). *See also, WFB Telecommunications, Inc. v. NYNEX Corp.*, 188 A.D.2d 257, 258-59, 590 N.Y.S.2d 460, 462 (1st Dep't 1992) (dismissing complaint, court rejected plaintiff's argument that certain documentary evidence may not be considered in support of a motion to dismiss under CPLR 3211(a)(7)).

In addition, on a motion to dismiss pursuant to CPLR 3211(a)(1), courts may consider documentary evidence which "conclusively establishes a defense to the asserted claims as a matter of law." *Scott v. Bell At. Corp.*, 282 A.D.2d 180, 183, 726 N.Y.S.2d 60, 63 (1st Dep't 2001); *see also, Bronxville Knolls, Inc. v. Webster Town Ctr. Partnership*, 221 A.D.2d 248, 634 N.Y.S.2d 62 (1st Dep't 1995) (dismissing complaint because agreements flatly contradicted liability); *Quatrochi v. Citibank, N.A.*, 210 A.D.2d 53, 618 N.Y.S.2d 820 (1st Dep't 1994) (dismissing complaint alleging breach of contract because allegations flatly contradicted by controlling agreement).

[5] *See* Medicaid Prescription Reimbursement Information by State - Qtr Ending September 2003, *available at* http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp (last visited November 30, 2003).

Medicaid program generally covers most prescription drugs dispensed in retail pharmacies, as well as drugs administered in other provider settings.[6]

Federal regulations require Medicaid reimbursement levels for prescription drugs to be the lesser of the provider's "usual and customary charges," or "estimated acquisition costs ["EAC"] plus reasonable dispensing fees established by the [state Medicaid] agency." 42 C.F.R. § 447.331(b)(1), (2). EAC is defined under federal law as the state Medicaid agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers." 42 C.F.R. § 447.301 (2003). The regulations do not require a State to "precisely ascertain a Medicaid provider's ***actual*** acquisition cost for a drug," and leave state Medicaid programs with latitude concerning how to determine "estimated acquisition costs." *See Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)*, HCFA Transmittal No. 77-13 (MMB), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 28,714 (Dec. 13, 1977) (emphasis added) (Defs. App. Ex. Z).

Many state Medicaid programs decided to use a discounted AWP as a proxy for estimated acquisition costs for some drugs.[7] States that made this decision did so despite numerous studies by the federal government that concluded that even discounted AWPs can be

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[6] In the landmark Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("2003 Medicare Act"), which was passed by Congress on November 25, 2003, Congress expanded Medicare coverage to most prescription drugs for the first time.

[7] *See Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs*, HCFA Medicaid Action Transmittal, No. 84-12, *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 34,157 (Sept. 1984), at ¶ 34,157 (Defs. App. Ex. A) (finding that as a result of the "considerable latitude" it had given the state Medicaid programs in the "design and administration of their Medicaid drug program[s]," many of the states had chosen to base their reimbursement methodologies on AWP). For the Court's convenience, this report, as well as other public documents cited herein, are included in the Appendix submitted herewith. Citations to the Appendix appear as "Defs. App. Ex. __."

substantially higher than actual acquisition costs. Several states -- including New York -- have exercised their discretion to set some (or all) of their drug reimbursement rates without regard to a drug's AWP.[8]

2. The Federal Government's Repeated Criticism of State Medicaid Programs' Selection of AWP as a Reimbursement Benchmark

The U.S. Department of Health and Human Services ("HHS") has repeatedly criticized state Medicaid agencies that have based prescription drug reimbursements on AWP. HHS has stressed to the states that AWPs do not reflect actual acquisition costs, but are instead often substantially higher.[9]

In 1984, HHS's Office of the Inspector General ("HHS IG") issued a report "alert[ing] Departmental management officials to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of average wholesale prices (AWP) in determining program reimbursement for prescription drugs." (Defs. App. Ex. A at 2). In its public report, which was available to all state Medicaid agencies, the HHS IG found that:

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[8] *See, e.g.*, N.Y. Soc. Serv. Law § 367-a(9)(b)(ii); N.Y. Soc. Serv. Law § 367-a(9)(a) (New York reimbursement set at AWP-12% for retail pharmacy drugs, but at actual acquisition cost for physician-administered drugs); 1 Tex. Admin. Code § 355.8549 (Texas does not use AWP at all for physician-administered drugs); Neb. R. & Regs. tit. 471, § 16-005.02C (same); Ala. Admin. Code r. 560-X-16-.06 (setting reimbursement rate at "Wholesale Acquisition Cost" ("WAC") + 9.2%); Mass. Regs. Code tit. 114.3, §§ 31.02, 31.04 (WAC+10%); R.I. Code R. 15 020 007 (WAC+5%); Md. Regs. Code tit. 10, § 09.03.01 (Lowest of AWP-10%, WAC + 10, distributor's price + 10%, and direct price + 10%); Ohio Admin. Code § 5101:3-9-05 (WAC+9% for claims submitted after April 30, 2002.

[9] As early as 1974 the Department of Health, Education, and Welfare ("HEW") planned to urge states to discontinue the use of AWP as a benchmark for Medicaid drug payment because AWPs "are frequently in excess of actual acquisition cost to the retail pharmacist." Proposed Reimbursement of Drug Cost, Department of Health, Education and Welfare, 39 Fed. Reg. 41,480 (to be codified at 45 C.F.R. pt. 250) (proposed Nov. 27, 1974) (Defs. App. Ex. B). Instead, "to achieve maximum savings to the Medicaid program," the agency initially proposed to forego AWP in favor of "actual acquisition cost" ("AAC"). *Id.* In comments on the proposed rule, many pharmacists requested that the agency let state Medicaid agencies continue to reimburse based on AWP as a means of boosting "pharmacy income." Limits on Payments for Drugs, 40 Fed. Reg. 34,516, 34,518 (Aug. 15, 1975) (Defs. App. Ex. C). HEW rejected the pharmacists' request because "AWP data are frequently inflated." *Id.* However, HEW dropped its insistence on AAC and permitted reimbursement on the basis of EAC because "of the administrative problems of States in determining AAC." *Id*

- "[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted ***significantly*** below AWP or list price." *Id.* at 3 (emphasis added).

- ". . . AWP cannot be the best -- or even an adequate -- estimate of the prices providers generally are paying for drugs. AWP represents a list price, and often does not reflect several types of discounts, such as prompt-payment discounts, total order discounts, end-of-year discounts or any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices." *Id.* at 16.

The HHS IG recommended that HHS revise its regulations to "eliminate the use of AWP" and require state Medicaid programs to use alternative methods to calculate estimated acquisition cost for Medicaid reimbursement purposes. *Id.* A 1989 HHS IG report repeated the findings of the 1984 report. *See Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in the Medicaid and the Medicare Prescription Drug Program, Report of the Office of Inspector General* (Oct. 3, 1989) at 1 (Defs. App. Ex. D).[10]

Following the 1989 HHS IG report, HCFA disapproved the Medicaid drug reimbursement plans of at least three states that proposed to use undiscounted AWPs to set drug reimbursement rates on the ground that AWP exceeded acquisition costs; and in at least two instances, HCFA refused to pay the federal share of reimbursements for states using undiscounted AWPs. *See Louisiana v. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HHS Dept. App. Bd. Aug. 13,

[10] Also in 1989, the Senate Special Committee On Aging issued a report recognizing that AWP exceeds actual drug prices. The Committee reported that "the [Veteran's Administration] achieves an average discount of 41% off [AWP] for single source drugs and 67% off the published AWP for multiple source drugs . . . [and] hospitals, HMOs and nursing homes that contract with wholesalers ***achieve discounts up to 99% of AWP.***" *Prescription Drug Prices: Are We Getting Our Money's Worth, A Majority Staff Report of the Special Senate Comm. of Aging*, S. Rep. 101-49 at 11 (1989) (Defs. App. Ex. E) (emphasis added).

1991). In the *Louisiana* case, more than a decade ago, the federal government filed a brief stating that "AWP has become like the 'sticker price on an automobile. It is the very highest price that anyone would be expected to pay for a drug product.'"[11]

3. The 1992 Study Focusing on New York Medicaid Reimbursement for Chemotherapy Drugs

In 1992 HHS-IG published a study that specifically focused on chemotherapy drugs administered by New York doctors -- the very type of drugs that are among the few drugs named in the State's complaints in these actions. *See* HHS IG, *Physicians' Costs For Chemotherapy Drugs* (Nov. 6, 1992) (Defs. App. Ex. G). The OIG reviewed drug reimbursement data for five physicians or physician groups in New York state. *See id.* at 1, 4. The report found that ***physicians' drug invoice costs were as much as 83% lower than published AWPs for the drugs studied***. Among the report's significant findings:

- "Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below AWP and that AWP is not a reliable indicator of the cost of a drug to physicians." *Id.* at 2, 5.
- "Red Book officials confirmed that the AWP is ***not designed to reflect physicians' costs.***" *Id.* at 5.
- "Our analysis disproved these misconceptions [such as the misconception that discounts below AWP usually apply only to multiple-source drugs] and established that high dollar volume chemotherapy drugs are available at a cost below AWP." *Id.* at 6.

[11] Brief For Respondent, *State of Louisiana v. Dep't of Health and Human Servs.*, 905 F.2d 877 (5th Cir. Jan. 12, 1990) (No. 89-4566), at 23 n.9 (Defs. App. Ex. F). In its opinion upholding HCFA's determination, the Fifth Circuit retraced much of the well-documented history of AWP outlined above and concluded that HCFA had properly prohibited the state from using an undiscounted AWP as the basis for estimating a drug's acquisition cost. *See Louisiana*, 905 F.2d at 877.

- "Analysis showed that each drug's cost was below the AWP and that the total cost for the drugs claimed was 48 percent of AWP." *Id.* at 6.

- In discussing a claim submitted by one provider, the report notes that the physician's actual cost for the three drugs covered was $253.78, whereas the combined AWP for the three drugs was $526.35. The largest gap was for Doxorubicin, where the AWP was $438.10 and the physician's acquisition cost was $180.00 *Id* at 6.

- The report concluded: "[W]e do not feel that AWP provides a useful measure of the acquisition cost for a drug to physicians." *Id.*

4. Press Reports on AWP

The difference between AWP and provider acquisition costs has been well publicized in the press as well. For example, in June 1996, an article appeared in *Barron's* that described AWP as "Ain't What's Paid." Bill Alpert, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices For Pharmaceuticals?*, Barron's, June 10, 1996 (Defs. App. Ex. H). Among other things, the article stated: "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices [to manufacturers] that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims." *Id.* It also described how physicians and others benefited from the "huge spread" between the "published wholesale prices ... and the far lower wholesale prices actually paid" by providers to drug manufacturers. *Id.* Numerous other press reports documented the gap between AWP and actual costs.[12]

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[12] *See also,* Robert Cohen & Edward R. Silverman, *Physicians Overcharge U.S. for Drugs; Cost to Medicare Put at $447 Million in 96*, Newark Star-Ledger, Dec. 27, 1997 ("But only Medicare, it seems, actually pays average wholesale prices. Most view this as nothing more than a benchmark."); Spencer Rich, *Battling the High Prices Medicare Pays for Drugs*, The Washington Post, Jan. 2, 1997 (AWP is "like the sticker price of an automobile;" "most doctors buy at a substantial discount and bill Medicare for a price based on AWP"); Eric D. Randall &

5. New York Medicaid's Decisions Concerning Use of AWPs

Under the New York State Medicaid drug program, prescription drugs are paid for differently by the State depending on whether the drug is provided by a "medical practitioner" or "pharmacies." N.Y. Soc. Serv. Law § 367-a(9)(a), (b). Significantly, this has been the practice in New York for many years. Beginning in 1980, New York decided to reimburse ***physicians*** based on "actual acquisition or invoice cost to the physician." N.Y. Soc. Serv. Law § 505.3(h)(1) (June 30, 1980). Since 1991, physician-administered drugs[13] are billed separately by the physician for his or her services in administering the drug and are paid for at "the ***actual cost*** of the drugs to the practitioners." N.Y. Soc. Serv. Law § 367(a)(9)(a) (emphasis added); *See* New York State Dep't of Social Services, *MMIS Provider Manual* at 7-107; 7-157 (revised July 2003) (Defs. App. Ex. K) (New York Medicaid will reimburse for injectibles and chemotherapy drugs at the invoice cost of the drug).

In stark contrast, pharmacist-provided drugs (those that are self-administered by the patient) are paid for at the "federal upper limit" established by the relevant federal agency or the lower of (i) EAC, as determined by State law or (ii) the actual dispensing pharmacy's "usual and customary price charged to the general public." N.Y. Soc. Serv. Law § 367-(a)(9)(b).[14] For purposes of pharmacy reimbursement, New York's legislature chose to define EAC as "the

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Michael Clements, *Drug Firms Handle Stress: Companies Breaking Out Batch of Deals*, USA Today, May 4, 1994 ("[D]iscounts offered to large buyers can be as much as 70% off the average wholesale price"); Elizabeth Sanger, *No Rx for Plans; Drug Plans Draw Pharmacists' Ire*, Newsday, Feb. 24, 1989 ("Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price") (articles collectively attached as Defs. App. Ex. I).

[13] Physician-administered drugs are injectible or intravenous drugs that are administered incident to a physician's services. These drugs are primarily used to treat cancer and the nausea resulting from chemotherapy.

[14] Pharmacists are also entitled to a "dispensing fee" of $4.50 per prescription in the case of "generic" drugs and $3.50 per prescription for "brand-name" drugs, as categorized by the prescription drug pricing service used by the State Department of Social Services. N.Y. Soc. Serv. Law § 367-a(9)(d).

average wholesale price of a prescription drug . . . as reported by the prescription drug pricing service used by the [State] department [of Social Services], less twelve percent thereof, and updated monthly by the department. N.Y. Soc. Serv. Law § 367-a(9)(b)(ii), as amended by Act of May 15, 2003, 2003 Session Law News of N.Y. Ch. 62, sec. Z2. [15] Other than referring to the prices set forth in commercial drug pricing services, there is no other state statutory or regulatory definition of "average wholesale price." New York's latest decision to set reimbursement for drugs dispensed in pharmacies at 12% below AWP, which modified the earlier rate of AWP-10% as of May 15, 2003, reflects a balancing of competing policy considerations between those who originally sought to reimburse at 15% below AWP in order to reduce state Medicaid program costs, and others, including the state's retail pharmacists, who argued that Medicaid reimbursement levels should be kept as high as possible in order to avoid pharmacy shut-downs and reductions in access to critical medications by New York Medicaid recipients, including Medicaid-eligible HIV/AIDS patients.[16]

Furthermore, the State Department of Social Services has the statutory power to require "[e]very manufacturer or wholesaler of drugs . . . [to provide] upon request of the department . . . any information pertaining to wholesale prices charged to pharmacists for any drugs available" under the State's Medicaid program and to "make the information available to the department on a monthly basis, or such other periodic basis as the department shall request." N.Y. Soc. Serv.

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[15] As set forth in the complaints, New York relies on "generally available compendia published by the price reporting services" as well as a computer file maintained by First Databank, to obtain AWPs. Complaints ¶ 16.

[16] *See, e.g.*, 2003 N.Y.L.S. S.226, L.2003, C.62, Part Z2, Supplement to Governor's Bill Jacket, Memorandum in Support, Part K, *Restructure the Medicaid Program, Contain Medicaid Costs, and Make Medicaid Managed Care Permanent*, at 20 (advocating AWP minus 15%), *compare*, Pharmacists Society of the State of New York, *Memorandum in Opposition, Executive Budget* (Feb. 2003), available at: http://www.pssny.org/Latest_News/2003/february/opposition_budget.pdf. (Defs. App. Ex. J) (opposing reductions in AWP-based reimbursements for a variety of policy reasons).

Law § 367-a(7). Thus, the State of New York has the ability under its own laws to obtain pricing information (in addition to AWPs) directly from manufacturers instead of using AWPs from commercial price reporting services.[17]

Finally, due to the co-payment structure for Medicaid beneficiaries under New York regulations, published AWPs have no effect on Medicaid beneficiary payments. Exercising its discretion to establish co-payments for its Medicaid recipients, New York has chosen to set co-payments at modest and flat amounts for prescription drugs -- $2.00 for brand-name prescriptions and $.50 for generic prescriptions. 18 NYCRR § 360-7.12 (f)(1). Because New York Medicaid beneficiaries' co-payments are fixed by New York law at flat rates, the amount of reimbursement paid by the New York Medicaid program for a drug has no impact on the co-payment at all.

6. New York's EPIC Program

EPIC is a voluntary state funded and administered program available to lower income New York residents 65 years of age or older who are not eligible for full Medicaid coverage. Complaints ¶ 13. EPIC covers prescription drugs dispensed by pharmacies, but not physician administered drugs. Complaints ¶ 13. EPIC currently reimburses for drugs at the lower of 90 percent of AWP or the pharmacy's usual and customary charge to the general public. N.Y. Exec.

[17] Moreover, as discussed below, the State actually obtains important additional pricing information directly from defendants as part of its EPIC Program.

Law § 547. j(i)(b).[18] EPIC participants must pay a co-payment for each drug purchased, but it is a ***flat*** co-payment based only in part on the price charged for the drug. *See* Complaints ¶ 13.[19]

In 1991, a Manufacturer Rebate Program was added to the EPIC statute. This provision requires that, in order for the EPIC program to cover a given pharmaceutical manufacturer's prescription drugs, the manufacturer must enter into a rebate agreement with the EPIC program. *See* N.Y. Exec. Law § 547-j(3)(a). Pursuant to the EPIC rebate agreement, manufacturers are required to submit rebate payments directly to EPIC. *See id.* The rebates are "designed to ensure EPIC pays the lowest price offered by manufacturers to all their customers, except some federal government agencies." EPIC Annual Report to the Governor and Legislature, October 1998 - September 1999.[20]

The EPIC Manufacturer Rebate Program mimics the provisions of the Federal Medicaid Rebate Program, which requires that pharmaceutical manufacturers report certain pricing information on a quarterly basis to a federal governmental agency, the Centers for Medicare and Medicaid Services ("CMS," formerly the Health Care Financing Administration, "HCFA"). *See* 42 U.S.C. § 11396r-8 *et seq.* ("Medicaid Rebate Statute"). Under the Medicaid Rebate Statute, manufacturers are required to report the "Average Manufacturer's Price" ("AMP") and "Best Price" at which certain drugs are sold. 42 U.S.C. § 1396r-8(b)(3)(A)(i). These terms, unlike

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[18] EPIC Program officials established this reimbursement system, which relies in part on AWP, after full access to the vast public record, described above, concerning the use of AWP as a reimbursement benchmark.

[19] EPIC co-payments, unlike Medicare co-payments, are not straight percentage co-payments that are proportionately affected by the amount paid for drugs by EPIC itself. Instead, EPIC beneficiaries pay flat co-payments that go up in several broad increments depending on the cost of the drug. *See* New York Dep't of Health Website: *Info for Consumers: Elderly Pharmaceutical Insurance (EPIC) Coverage Program*, available at: http://www.health.state.ny.us/nysdoh/epic/faq.htm (last visited Nov. 30, 2003) (relevant portions attached as Def. App. Ex. L).

[20] The EPIC annual report is available at the New York Department of Health's website: http://www.health.state.ny.us/nysdoh/epic/ar98-99.pdf (last visited Nov. 30, 2003).

AWP, are defined by federal statute. "Average Manufacturer's Price" means "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. 1396r-8(k)(1). "Best Price" means "the lowest price available from the manufacturer…to any wholesaler, retailer, provider, health maintenance organization, non profit entity, or government entity within the United States." 42 U.S.C. § 1396r-8(c)(1)(C). AMP and Best Price information is used by CMS to calculate rebate payments to be made from drug manufacturers to participating state Medicaid programs pursuant to the terms of their federal Medicaid rebate agreements.

Because the New York EPIC Manufacturer Rebate Program is modeled after the Federal Medicaid Rebate Program, ***EPIC requires that pharmaceutical manufacturers report the same pricing information to EPIC that manufacturers are required to report to CMS, including AMP and "Best Price" data.***[21] Thus, since the early 1990s, under the EPIC Manufacturers Rebate Program, the New York EPIC Program has had detailed AMP and "Best Price" data from many drug companies, including defendants.

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[21] *See, e.g.*, New York Dep't of Health Website: *Standard Contract For Manufacturers Drug Rebates*, at II(a) (Defs. App. Ex. M at 5-7) ("Within thirty (30) days of the end of each calendar quarter, the Manufacturer will provide EPIC with an *identical copy* of the data required for all Covered Outpatient Drugs by the Centers for Medicare and Medicaid Services for the Medicaid Drug Rebate Program pursuant to Section 1927 of the Social Security Act (42. U.S.C.A. 1396 r-8)." (emphasis added) (available at http://www.health.state.ny.us/nysdoh/phforum/notices/rfp/epic/attachment_16_-standard_contract_for_manufacturers_drug_rebates.doc (last visited Nov. 30, 2003); *see also*, N.Y. Exec. Law § 547-j(3)(c) (providing that the "rebate agreement shall also provide for…provision of information to the program…").

B. The Medicare Part B Drug Program

The law and history of drug reimbursements under Medicare Part B must also be considered, because the State seeks to recover for allegedly excessive drug co-payments made by New York citizens covered by Medicare Part B. Unlike Medicaid, Medicare Part B has historically provided only a ***limited*** prescription drug program, primarily covering physician-administered drugs such as cancer treatments. As described below, when the Medicare Part B drug benefit became effective in 1991, the federal government chose to base reimbursement for covered drugs on AWPs, despite having previously urged state Medicaid programs not to use AWP as a reimbursement benchmark. This was the result of a deliberate policy choice by Congress to permit oncologists to receive extra payments for drug reimbursement in order to compensate them for other costs, not reimbursed by Medicare, associated with administering the drugs.

The long-standing linkage between Medicare reimbursement for physician-administered drugs and reimbursement for the professional services of oncologists has been underlined by two recent events. First, in August 2003, CMS proposed reductions in Medicare Part B pharmaceutical reimbursement in tandem with increases in physician reimbursement for services. *See* 68 Fed. Reg. 50428 (Aug. 20, 2003). Second, in the landmark Medicare legislation passed on November 25, 2003, Congress superceded CMS's proposed rules by legislatively mandating phased reductions in reimbursement for certain Part B drugs as a corollary to increased reimbursement for oncologists' services. *See* 2003 Medicare Act, § 303.

1. Medicare Part B Framework

The Medicare program provides basic and supplementary health insurance to individuals age 65 and older and to other qualifying individuals. Complaints ¶¶ 6-10; *see, also* 42 U.S.C. §§ 1395-1395pp (2000). Medicare is governed and administered by CMS, a branch of the HHS. Congress has authorized the Secretary of HHS to promulgate regulations setting limits on the levels of Medicare costs that will be reimbursed.

Part B of Medicare established a voluntary, federally subsidized program of supplemental medical insurance that reimburses beneficiaries for, *inter alia*, part of the cost of certain limited categories of drugs, including those administered by injection or infusion by physicians and their staff in the doctor's office and other outpatient settings, or by other specified healthcare providers at other sites (collectively "physician-administered drugs"). Complaints ¶ 9; *see* 42 U.S.C. § 1395k(a)(1). Anti-cancer chemotherapy drugs and anti-emetics constitute "the dominant type of physician-administered drugs covered by Medicare." Complaints ¶ 9. These drugs are among the few that are typically purchased not by pharmacists but by physicians. The physician chooses which drug to administer, bills Medicare for the drug, and is reimbursed directly by Medicare at the applicable reimbursement rate (currently 95% of AWP).[22] The Act generally provided beneficiaries coverage for 80 percent of the allowable amount for a covered drug. Complaints ¶ 10; *see* 42 U.S.C. § 1395l(o). The beneficiary is responsible for paying the remaining 20 percent to the health care provider who administers the drug. *Id.*

[22] For the more typical retail pharmacy-dispensed drug, of course, the pharmacist who buys and submits reimbursement for the prescription drug does not make the prescribing decision -- the physician does.

2. The Decision to Use AWP for Medicare Reimbursement

When Congress amended the Medicare Act in 1989 to provide additional benefits (including the Part B prescription drug program), the statute provided that Medicare would reimburse for the additional services based on the physician's "actual charge" (i.e., whatever physicians actually charged their patients), or pursuant to a fee schedule to be developed by HCFA. *See* Pub. L. No. 101-239 § 6102(a) (1989) (codified in part at 42 U.S.C. § 1395w-4(a) & (j)(3)). HCFA did not, however, establish a specific fee schedule for the physician-administered drugs. Instead -- notwithstanding its awareness of the issues created by an AWP-based reimbursement system gained through the Medicaid program -- HCFA in 1991 proposed a rule instructing all carriers "to base payment for drugs at 85% of the national [AWP] of the drug (as published in the Red Book and similar price listings)." 56 Fed. Reg. 25792-01, 25800 (June 5, 1991) (citing reports finding that pharmacists paid significantly less than AWP for drugs).

In response to this proposed regulation, HCFA "received a great many comments on [the drug reimbursement] issue, primarily from oncologists indicating that our 85 percent standard was inappropriate." 56 Fed. Reg. 59502-01, 59524 (Nov. 25, 1991). These oncologists argued in 1991 that Medicare should pay them more than the price they paid to purchase drugs in order to make up for the fact that Medicare underpays them for their professional services and to cover overhead costs, such as inventory costs, waste, and spoilage costs associated with chemotherapy drugs. *See id.* Commentators advised that unless Medicare paid oncologists a higher amount, some oncologists would stop administering chemotherapy in their own offices and would instead do so in hospital settings, leading to higher overall costs to Medicare. *See id.*

In response to these comments, HCFA rejected its proposed 85% of AWP rule in favor of a final regulation that set the allowable Medicare reimbursement amount as the lesser of (1) 100% of AWP, or (2) estimated acquisition cost ("EAC"), as determined by Medicare carriers' surveys of the prices paid for the drug, taking into account additional cost factors such as inventory, waste, and spoilage. *See id.* at 59621, *codified at* 42 C.F.R. § 405.517 (1991) (now superseded). However, Medicare carriers reported that they had difficulty compiling accurate EAC data. *See Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, Joint Hearing Before the Subcomm. on Health and the Subcomm. on Oversight and Investigations of the House Comm. on Energy & Commerce*, 107th Cong. at 88 (2001) (Defs. App. Ex. N); Letter from HHS Secretary Donna E. Shalala to Hon. Thomas Bliley, Chairman, House Comm. on Energy and Commerce (May 31, 2000) (Defs. App. Ex. O) (noting that Medicare carriers stated they were unable to obtain accurate acquisition cost data from 1992 to 1997); *see also*, 68 Fed. Reg. 50429 (Aug. 20, 2003) ("because of statistical sampling concerns . . . the EAC was never implemented"). As a result, from 1991 to 1997, the carriers allowed Medicare reimbursement for covered drugs at 100% of AWP, despite numerous additional studies by HHS and other governmental agencies, including the materials described above, and press reports that showed that AWP far exceeded the providers' acquisition costs.[23]

3. Medicare Reimbursement Rate Is Changed in 1997 to 95% AWP

Congress and the Administration debated changes to the Medicare drug reimbursement system in connection with the Balanced Budget Act of 1997 ("BBA"). In the end, Congress

[23] The government maintained this AWP-based reimbursement system despite the issuance of at least ten additional HHS IG and GAO reports between the time of HCFA's 1991 rulemaking and the enactment of the Balanced Budget Act of 1997, all criticizing the state's use of AWP in Medicaid and repeatedly emphasizing that AWP represents an undiscounted price that exceeds the acquisition cost paid by pharmacies and physicians (collectively Defs. App. Ex. P).